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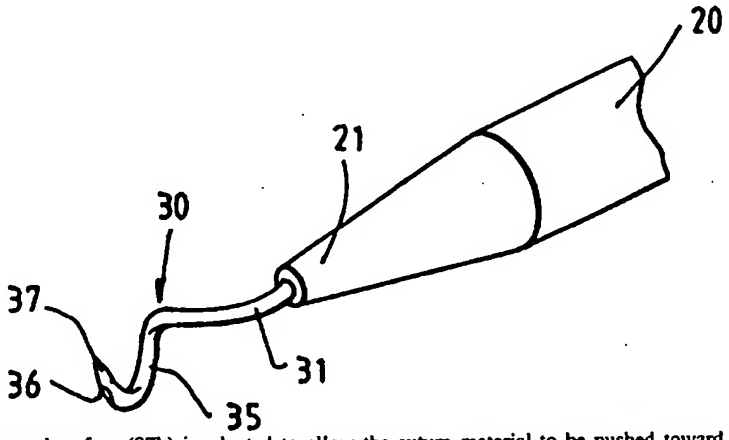
(54) Title: SURGICAL INSTRUMENTS

(57) Abstract

The invention relates to instruments for surgery, particularly endoscopic surgery. In a first aspect the invention provides an instrument for placing sutures comprising an elongate shaft (20) terminating in a head (30) with a needle (31) having a tip (37), wherein said needle (31) has means (36) for releasable retaining suturing material and wherein said head (30) is profiled so that axial rotation of the shaft (20) moves the tip (37) forwardly of the instrument to draw suturing material forwardly and through tissue. In a second aspect the invention provides an instrument for pushing and retrieving ligatures comprising an elongate shaft (70) terminating in a head (80) with a suture material engaging portion (85), said engaging portion (85) comprising first and second opposed curved surfaces (87a, 87b) wherein the first curved surface (87b) is adapted to allow the suture material to be pushed toward a patient and the second curved surface (87a) is adapted to allow the suture material to be pulled away from a patient.



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Title: Surgical Instruments

The present invention relates to instruments useful for performing surgery. In particular the invention relates to instruments for use in operations in which it is difficult to place stitches or sutures.

Sutures are necessary in surgery to hold tissues in place while healing occurs or to position organs or tissues in a certain location and to fix them in that particular location.

In some situations it is difficult to insert sutures. For example, in operations such as Burch Colposuspension which is used to treat female stress incontinence, placement of sutures is difficult.

The essence of this operation is the elevation of the peri-vaginal fascia adjacent to the bladder neck towards the ilio pectineal ligament on the upper medial aspect of the superior pubic ramus. Traditionally, two to three stitches of non-absorbable material are used on each side. The dense fibrous nature of the ligament requires a heavy gauge needle for successful transfixion. There is considerable individual variation in the precise anatomy of the ligaments. As a consequence, exact angle of entry of the needle into the ligament varies. Traditionally, the operation is performed through a transverse supra-pubic incision.

In common with many other gynaecological procedures, Burch Colposuspension has attracted the interest of endoscopic surgeons. The advantages of endoscopic surgery are well documented.

The crucial step of transfixion of the ilio pectineal ligament is difficult to perform using conventional endoscopic instruments. Suitable heavy gauged needles are not readily available. Access to the superior aspect of the pubic bone, enabling accurate deep transfixion is difficult. This leads some operators to

compromise. The ligature may be stapled to the ligament, or alternatively one stitch per side, instead of two or three, may be used. Transfixion may be less than perfect. Any of these could compromise the long-term outcome for the patient.

The aneurysm needle as used in conventional surgery, comprising a shaft and a curved portion disposed at right angles to the shaft, is not suitable for endoscopic surgery.

The aim of the present invention is to provide instruments which allow sutures to be placed in a patient more easily and/or quickly.

In a first aspect the invention provides an instrument for placing sutures comprising an elongate shaft terminating in a head with a needle having a tip, wherein said needle has means for releasably retaining suturing material and wherein said head is profiled so that axial rotation of the shaft moves the tip forwardly of the instrument to draw suturing material forwardly and through tissue.

The term "shaft", refers to a shaft or stem. In addition, the instrument may also comprise a handle. If a handle is not provided the shaft should be of sufficient length to allow the instrument to be manipulated, or to allow a handle to be joined thereto.

The term "head" refers to the end of the instrument which engages a patient's tissue.

The term "needle" refers to a means that is sufficiently sharp to puncture tissue to make an opening for the suture.

The term "means for releasably retaining suturing material" refers to a means on the needle for holding the suturing material. Typically, this will be an aperture or "eye" of sufficient size to retain the suturing material until the suture is placed. Preferably the aperture is located close to the tip of the needle. The aperture may

be suitable for threading by suturing material so that the material runs in the same direction as the shaft of the instrument or in a position transverse thereto. Preferably the aperture is adapted to be threaded by suturing material transverse to the direction of the shaft of the instrument.

Preferably the profile of the head is helical or partly helical in shape. The term "partly helical" means that the end portion comprises a part spiral or part helix. However, the curved sections of the spiral may not be completely arcuate; the curves may form sharper angles. The part helix may be left-handed or right-handed. Preferably the part helix is concentric with the longitudinal axis of the shaft, although it may be slightly off-set therefrom. This substantial concentricity enables the placer to be inserted through a small diameter endoscopic cannula.

In another aspect the invention provides an instrument for pushing and retrieving ligatures comprising an elongate shaft terminating in a head with a suture material engaging portion, said engaging portion comprising first and second opposed curved surfaces wherein the first curved surface is adapted to allow the suture material to be pushed towards a patient and the second curved surface is adapted to allow the suture material to be pulled away from a patient.

The first and second curved surfaces may be provided by any convenient means such as a wire or rod bent to provide essentially two adjacent hook portions facing in opposite directions. This may be provided by a wire or rod bent into a profile which resembles the letter "s", "I" or the Greek letter omega, for example.

Preferably the surfaces are provided by a stem shaped in an appropriate configuration and attached to a shaft to facilitate manipulation of the instrument.

Preferably the instrument comprises a stem with a tip, wherein the tip is offset from the longitudinal axis

of the stem.

Even more preferably the suture engaging portion comprises an elongated stem section having a substantially s-shaped or I-shaped configuration at the end thereof, wherein top or bottom of the s-shaped or I-shaped configuration runs substantially in line with a longitudinal axis of the shaft and where the s-shaped of I-shaped configuration is located distally from the shaft.

The term "substantially in line with a longitudinal axis of the shaft" means that the top or bottom is more or less in line with the longitudinal axis, i.e. not disposed at right angles thereto.

Preferably the substantially s-shaped configuration is somewhat compressed to form less round curves.

Preferably the stem of the ligature pusher retriever is formed from steel wire or rod and is round in cross section. The advantage of such a stem is that it is unlikely to fray the suture because there are no sharp curves and the rounded nature of the rod does not abrade the suturing material. In addition the instrument combines two functions in one because the s- or I-shaped configuration allows sutures to be pushed and pulled by merely repositioning the instrument inside the cannula, for example.

The invention also relates to a kit comprising the placer and/or pusher retriever in combination with two other instruments. These are described in the preferred embodiments below.

The invention will now be described with reference to the following non-limiting drawings.

Figure 1 illustrates the suture placer according to a preferred embodiment of the invention in perspective view and shows the full instrument.

Figure 2 illustrates an enlarged perspective view of the suture placer.

Figure 3 illustrates a side view of the suture placer.

Figure 4 illustrates a plan view of suture placer.

Figure 5 illustrates an end view of the suture placer.

Figure 6 illustrates a detailed perspective view of the ligature pusher retriever.

Figure 7 illustrates a side view of the ligature pusher retriever.

Figure 8 illustrates a plan view of the ligature pusher retriever.

Figure 9 illustrates detailed perspective view of another embodiment of the suture placer of the invention.

Figure 10 illustrates a side view of the suture placer.

Figure 11 illustrates a plan view of the suture placer.

Figure 12 illustrates a perspective view of the suture picker suitable for use with the other instruments.

Figure 13 illustrates a side view of the suture picker.

Figure 14 illustrates a plan view of the suture picker.

Figure 15 illustrates a perspective view of the abdominal wall elevator, or "toggle".

Referring to the figures, suture placer 1 comprises a handle 10 and a shaft 20 which extends therefrom. Handle 10 may be of any convenient configuration for gripping the instrument.

Shaft 20 comprises a rod which narrows at an end 21 distal from handle 10.

Head 30 comprises a needle 31 which extends from shaft 20. The forwardly angled, curved portion of head 30 comprises a partly helical or spiral portion 35 and with tip 37 with a sharp point 37a. The sharp point 37a

facilitates puncturing of tissue. The forward angle may be quite pronounced (as in Figs 1-4) or slight (as in Figs 9-11). Helical or spiral portion 35 may be likened to a part corkscrew and may be right-handed or left-handed in orientation. Preferably the instruments are supplied in pairs which are mirror images of each other. Preferably the arc or radius of spiral portion 35 is not larger than the diameter of the shaft 20 as shown in Figure 5. This facilitates passage through endoscopic instruments.

Aperture or eye 36 is located at the tip 37 of head 30. Aperture 36 may be positioned such that the needle may be threaded in any direction but preferably it is adapted to be threaded transverse to the direction in which the shaft runs (i.e. front to back).

Ligature pusher retriever 50 comprises a handle (not shown) and shaft 70 similar to suture placer 1. Shaft 70 narrows at one end 71 distal from the handle similar to suture placer 1.

The head 80 comprises suture material engaging portion 85 which comprises a stem 80a. Stem 80a basically comprises a smooth rod or wire with a tip 86a which is off-set from the stem 80a. Engaging portion 85 has a substantially s- or z-shaped configuration 87 at an end distal from shaft 70 comprising essentially two hook portions 87a and 87b facing in opposite directions. These provide surfaces for pushing and pulling the suture material. Other configurations such as I-shaped are also contemplated. Top 86 of s-shaped configuration 87 runs substantially in line with the long axis of shaft 70. S-shaped configuration 87 does not extend further widthwise than the diameter of shaft 70.

The instruments may be made of any suitable dimension. Preferably the instruments are of a size suitable for endoscopic surgery.

Conveniently the suture placer instrument may be about 390 mm long including the handle and shaft.

Preferably the shaft is 9 mm in diameter and the spiral has a radius of 4.5 mm. The spiral preferably has a forward angle of about 5° to about 30°. Other forward angles are also contemplated. Varying angles are required to accommodate the differing anatomy of individual ilio-pectineal ligaments, for example.

The ligature pusher retriever instrument has a similar handle portion and shank portion which may conveniently be 390 mm in length. Similarly the shaft portion is conveniently 9 mm in diameter. The s-shaped configuration is preferably 1.5 mm.

These instruments may be made of any convenient material. For example the handles and shanks may be made of stainless steel and the needle may be made from chrome-vanadium steel heat shrunk on to the shaft. Alternatively the instruments may be made of suitable synthetic materials such as plastics.

The suture picker 90 is similar to the other two instruments in that it has handle (not shown) and shaft portion 100. Similarly the shaft narrows at an end distal to the handle and has a head with a suture engaging portion 110 extending therefrom. The distal end of the suture engaging portion is disposed essentially at right angles to the long axis of the shaft and stem 120 has a slight bend 120a mid-way along its length.

The abdominal wall elevator (toggle) 150 comprises a substantially cylindrical rod having a bore 160 located mid-way along its length and a bore (161, 162) at each end. The bores (160 to 162) run transverse to the longitudinal axis of the toggle. Circumferential grooves (160a - 162a) are provided adjacent to bores 160 - 162. These grooves help to locate threads which have been threaded through the bores onto the toggle. The toggle may be threaded with lines, dropped into a port inside a patient's abdomen, the lines retrieved and secured outside the abdomen so as to elevate the abdominal wall. The toggle

is preferably 8 mm thick and 60 mm long.

Traditionally sutures are placed with a standard surgical needle which has basically a shallow "U"-shape. Thus a needle and a suture driver are needed to place and tie a suture.

The suture placer instrument of the present invention allows the needle and driver to be combined into the one instrument. The fact that the instrument does not have to be moved around greatly in order to get the needle to "bite" into the tissue means that the instrument may be used in endoscopic surgery. The forward angle of the needle of instrument means axial rotation, without lateral or other movement of the instrument, is sufficient to place the suture. Once placed, the loop formed by the suture material may be withdrawn from the eye of the instrument by the ligature pusher retriever. The suture knot may then be tied extracorporeally and pushed down to its intended position within the patient with the ligature pusher retriever.

CLAIMS

1. An instrument for placing sutures comprising an elongate shaft terminating in a head with a needle having a tip, wherein said needle has means for releasably retaining suturing material and wherein said head is profiled so that axial rotation of the shaft moves the tip forwardly of the instrument to draw suturing material forwardly and through tissue.

2. The instrument of claim 1 wherein the profile of the head is at least partly helical.

3. The instrument of claim 1 or claim 2, wherein the head does not extend in a radial direction beyond the width of the shaft.

4. The instrument of claim 2 wherein said helix is substantially concentric with the longitudinal axis of the shaft.

5. The instrument of claim 2 wherein said helix is right handed or left handed.

6. The instrument of claim 1 wherein means for releasably retaining suturing material comprises an aperture adapted to be threaded in a direction transverse to the needle.

7. An instrument for pushing and retrieving ligatures comprising an elongate shaft terminating in a head with a suture material engaging portion, said engaging portion comprising first and second opposed curved surfaces wherein the first curved surface is adapted to allow the suture material to be pushed toward a patient and the second curved surface is adapted to allow the suture material to be pulled away from a patient.

8. The instrument of claim 7 wherein said first and second surfaces are provided respectively by two adjacent hook portions.

9. The instrument of claim 7 or claim 8 wherein said suture engaging portion comprises a substantially s-shaped or I-shaped configuration.

10. The instrument of claim 7 comprising a shaft located distally from said suture engaging portion, wherein said suture engaging portion does not extend in a radial direction beyond the width of the shaft.

11. A surgical kit comprising the instrument of claim 1 and/or the instrument of claim 2 together with the suture picker and/or toggle as described herein.

12. A surgical kit comprising two instruments of claim 2, one having a left handed helix and the other having a right handed helix.

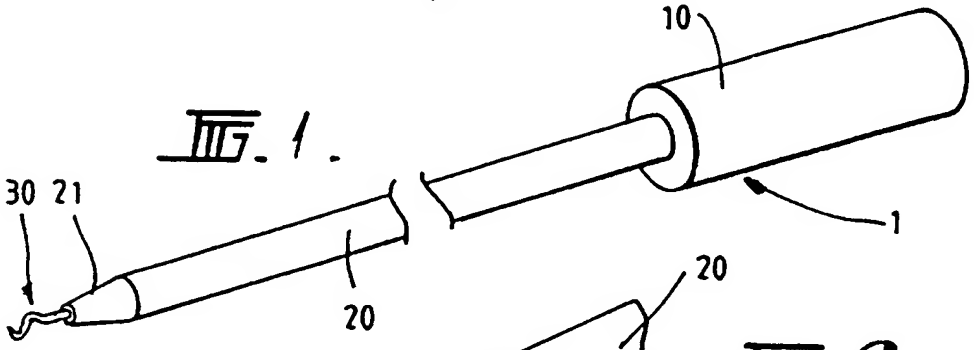


FIG. 1.

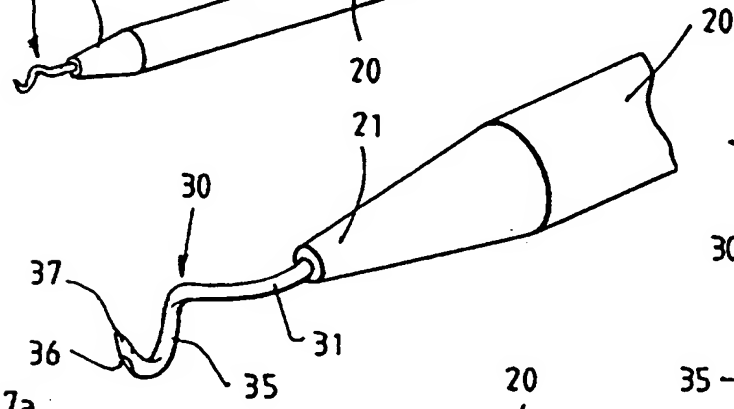


FIG. 2.

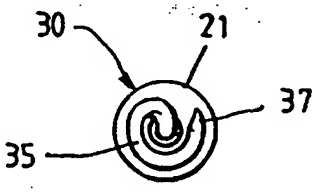


FIG. 5.

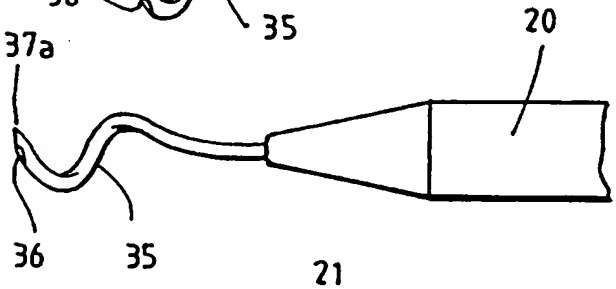


FIG. 3.

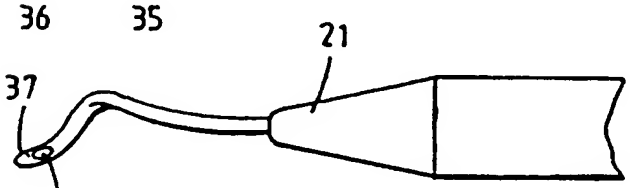


FIG. 4.

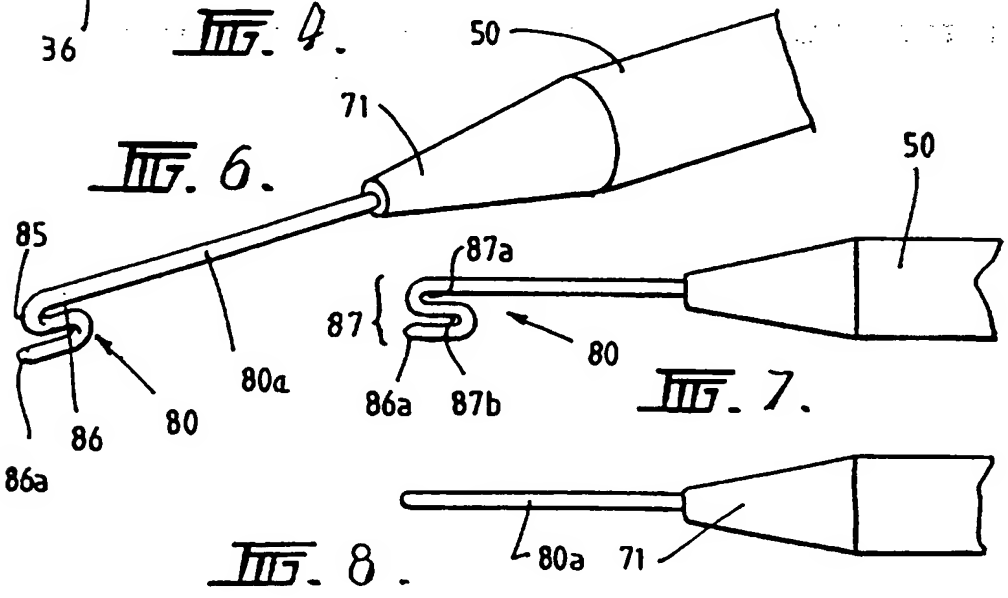
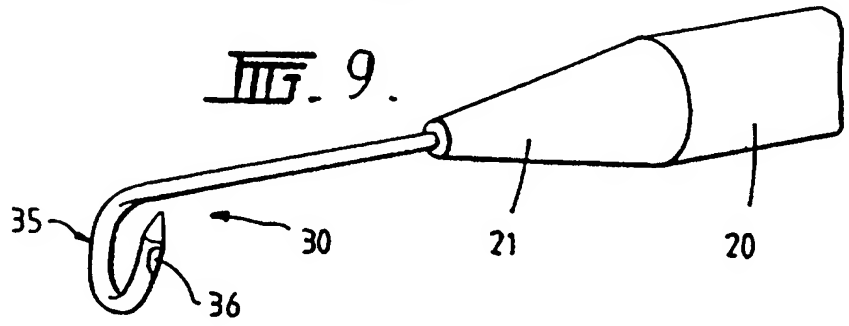


FIG. 6.

FIG. 7.

FIG. 8.

FIG. 9.



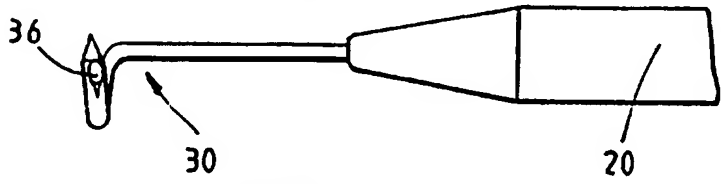


FIG. 10.

FIG. 11.

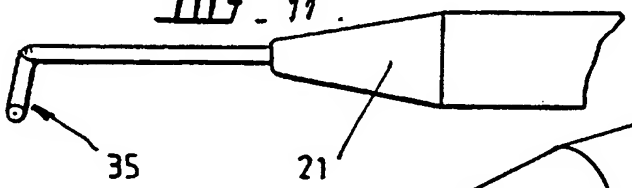


FIG. 12.

FIG. 13.

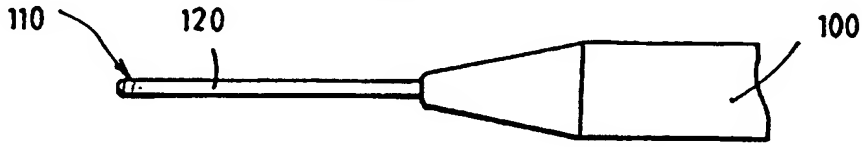


FIG. 14.

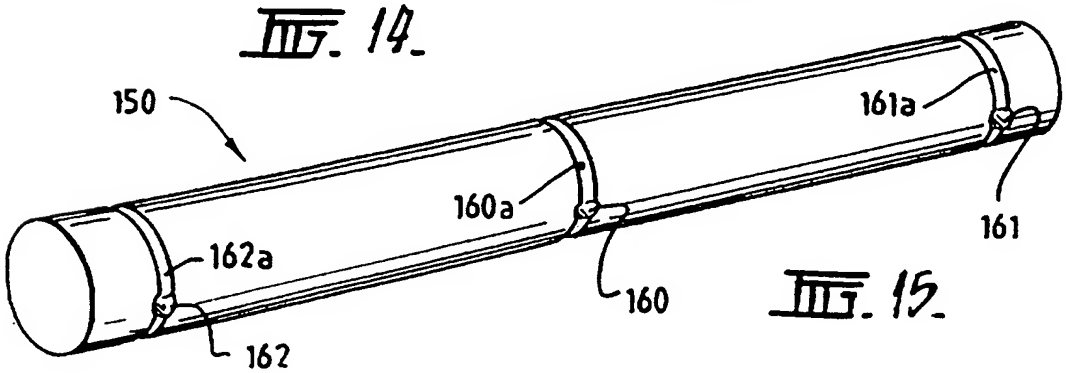


FIG. 15.

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00680

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC : A61B 17/03 17/04 17/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4204541 A (KAPITANOV) 27 May 1980 column 4 lines 3-7	1-5, 12
X	DE 4114204 A (PIER) 5 November 1992 column 3 lines 1-6	1-5, 12
X	Derwent Abstract Accession No. 88-082918/12 Class P31, SU,A, 1331495 (DNEPR MED INST) 23 August 1987 abstract	1-6, 12

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 January 1997	31 JAN 1997

Name and mailing address of the ISA/AU
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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00680

C (Continuation) **DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 4304353 A (WURSTER) 28 April 1994 figure 6	1
X	EP 537493 A (RICHARD WOLF GMBH) 21 April 1993 figure 2	7-10
P,X	AU 39073/95 A (LINVATEC CORP.) 27 June 1996 page 10 lines 1-6, figures 8 and 9	1-10, 12
P,X	WO 96/20649 A (AMERICAN CYANAMID CO) 11 July 1996 page 2 lines 26-33	7, 8, 10

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00680

Box 1 Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims 1-6 and 12
an instrument for placing sutures
2. Claims 7-10
An instrument for pushing and retrieving sutures
3. Claim 11
A kit comprising the first invention together with a suture picker and/or a toggle

as reasoned on the extra sheet:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:1-10, 12

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00680

Box II continued

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are three inventions:

1. Claims 1-6 and 12 directed to an instrument for placing sutures comprising an elongate shaft and a needle, whereby rotation of the shaft moves the needle forward. This rotation moving the needle forward is considered to comprise a first "special technical feature".

2. Claims 7-10 directed to an instrument for pushing and retrieving sutures, comprising first and second opposed curved surfaces. It is considered that these opposed curved surfaces comprise a second "special technical feature".

3. Claim 11 directed to a kit comprising the invention defined by claim 1 or 2, together with a suture picker and/or toggle as herein described.

As the first and second inventions do not share either of the technical features identified, a "technical relationship between the inventions does not exist. Therefore the two groups of claims do not relate to one invention.

Inventions 1 and 3 also do not relate to one invention when claim 11 defines the invention defined by claim 1 or 2 and the toggle as herein described. There is lack of unity a posteriori between inventions 1 and 3 because the subject matter common to the inventions (i.e. claims 1 and 2) is known. For examples in the prior art disclosing the subject matter of claims 1 and 2, see

(a) DE 2801096 A (MED TECH RES INST) 27 July 1978
(b) DE 4114204 A (PIER) 5 November 1992

Therefore the features common to the inventions are lacking in novelty, and lack of unity a posteriori exists.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU 96/00680

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	4204541	DE JP	2801096 53115595	CA	1131090	FR	2377796
DE	4114204						
SU	1331495						
DE	4304353	US	5545148				
EP	537493	DE	4133966	US	5385568		
AU	39073/95	EP	717957	JP	8215200	US	5499991
WO	9620649	AU	46109/96				

END OF ANNEX